DEPARTMENT OF HEALTH AND HUMAN SERVICE

Southwest Region

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Food and Drug Administration
Denver District Office
Bldg. 20-Denver Federal Center
P.O. Box 25087
6th Avenue & Kipling Street
Denver, Colorado 80225-0087
Telephone: 303-236-3000
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June 26, 2000

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Kevin R. Mason
Owner
Honey Smoked Fish Company LLC
26279 Highway 74
Kittredge, Colorado 80457

Ref #: DEN-00-27

WARNING LETTER

Dear Mr. Mason:

We inspected your firm, located at 26279 Highway 74, Kittredge, Colorado, on May 17 and 22, 2000 and found that you have serious deviations from the Seafood HACCP Regulations, Title 21, Code of Federal Regulations, Part 123 (21 CFR Part 123). These deviations, some of which were previously brought to your attention, cause your products, i.e. smoked salmon and smoked trout, to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the Seafood HACCP Regulations through links in FDA's home page at www.fda.gov.

The deviations were as follows:

You must have a written HACCP plan that lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3). However, your firm's HACCP plan for smoked salmon and trout does not list the critical limits to identify a minimum brine time, minimum salt concentration of the brine or set and identify a minimum ratio of brine to fish or a maximum fish thickness, to control potential *Clostridium botulinum* formation. Also, your firm's HACCP plan does not list a critical limit at receiving to identify potential aquaculture drug contamination of your raw fish.

You must implement the monitoring procedures listed in your HACCP plan, to comply with 21 CFR 123.6(b). Your procedures state that you will obtain annual reports from all suppliers to determine the levels of environmental chemical contaminants and pesticides found in your raw fish.

There is no evidence that you have obtained these annual reports from your suppliers. Your firm also failed to follow the monitoring procedures for the critical control points of receiving and storage. Your plan states that you will monitor your cooler temperature twice daily and record the readings in your storage logs. It also states that you will monitor and record the internal temperature of incoming fresh salmon fillets, trout fillets, and the truck trailer holding area before accepting shipment. Our inspection revealed several instances where you failed to perform these monitoring and documenting operations.

You must have a HACCP plan that lists monitoring procedures for each critical control point, to comply with 21 CFR 123.6(c)(4). Your firm's HACCP plan for smoked salmon and trout states that annual samples for salt levels will be taken and sent to an independent lab for analyses. This is not adequate to control for *Clostridium botulinum* formation. Our inspection found that only one sample was analyzed in 1998. This sample did not indicate which products were analyzed or the size/weight of the fish. You need to test all of your products on a periodic basis to demonstrate that the minimum 3.5 percent salt level is always achieved. After demonstrating that your process consistently achieves this desired level, an annual confirmation test may be taken to assure that your products remain in compliance.

You must take an appropriate corrective action when a deviation from a critical limit occurs, to comply with 21 CFR 123.7(a). However, your firm did not take a corrective action to control the temperature of your products at storage. Review of your storage logs indicated several instances where the maximum cooler temperature allowed by your HACCP plan was exceeded. There is no evidence that any corrective action was taken by your firm.

You have not maintained sanitation control records as required by 21 CFR 123.11(c). Specifically, you failed to have records showing the safety of water used in processing; the condition and cleanliness of food contact surfaces; the prevention of cross-contamination; the maintenance of hand washing and toilet facilities; the protection of food, food packaging and food contact surfaces from adulteration with contaminants; the proper labeling, storage and use of toxic compounds; the control of employee health conditions or the exclusion of pests from your facility. This deficiency was also previously brought to your attention in our letter dated October 13, 1998.

We are also aware that the labeling of your products, Honey Smoked Salmon, Honey Smoked Trout, Teriyaki Honey Smoked Salmon, and Teriyaki Honey Smoked Trout, do not include all of the ingredients used in the production of these products. Specifically, your firm uses Teriyaki Marinade and Sauce, PAM and a lemon juice mixture which do not appear on your labeling. This causes these products to be misbranded under Section 403(a)(1) of the Act in that the identity statement or ingredients' statement do not list all the ingredients as required by 21 CFR 101.4.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your products and/or enjoin your firm from operating.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations.

You may wish to include in your response, documentation such as copies of temperature monitoring records, sanitation control records, and a copy of your written HACCP plan or other useful information that would assist us in evaluating your corrections. If you cannot complete all the corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Regina A. Barrell, Compliance Officer, at the address listed above. If you have questions regarding any issues in this letter, please contact Ms. Barrell at (303) 236-3043.

Sincerely,

Thomas A. Allison
District Director